



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 22 2004

5 3 3 2 104 JAN 27 19 42

John R. Mattingly
Mattingly, Stanger & Malur
1800 Diagonal Road
Suite 370
Alexandria, VA 22314

Docket No. 2003P-0366/CP1

Dear Mr. Mattingly:

This letter responds to your citizen petition dated August 12, 2003, requesting that the Food and Drug Administration (FDA) amend its approval of Prilosec OTC to require that it be sold under a different brand name to reduce consumer confusion and decrease the potential for misuse of the product.

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering the issues raised in your petition as well as recently received comments in support of the petition. We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003 P-0366

LET 2